SEP 3 2002

Section 4

510(k) Summary

K021848

General Information:

Submitted by: Clarus Medical, LLC
1000 Boone Avenue North
Minneapolis, MN 55427

Contact: Tom Barthel, President
Telephone 763-525-8401
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Summary Date May 8, 2002

Device Name: Model 1150 Clarus Straight Firing Laser Fiber
Model 1160 Clarus Side Firing Laser Fiber

Common Name: Low OH Laser Fiber

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.

Predicate Devices:

510(k) Number	*Description*	*Manufacturer*
K922881	Model 1150 Laser Fiber	Clarus Medical, LLC
K011207	Reusable Holmium Fiber	Laser Peripherals
K973172	Resposable Holmium Bare Fibers	Trimedyne, Inc.
K992083	Scatter Free Lateral Emitting Fiber	Laser Peripherals
K972272	Laser Peripherals Holmium Bare Fibers	Laser Peripherals

Intended Use:

The Clarus Model 1150 Straight Firing and the Clarus Model 1160 Side Firing Laser Fibers may be used both intraoperatively and percutaneously through regulatory cleared delivery systems.

Device Description:

General

This 510(k) submission is a modification of the existing Clarus Model 1150 Laser Fiber previously filed as K922881 and found to be substantially equivalent by the FDA on November 16, 1992. The original 510(k) device was a single-use, straight firing laser fiber with a fiber indicated for laser disc decompression where the laser is used to remove inner disc material. The laser fiber core ranges from 380 – 600 microns. The modifications represented by this submission are the addition of a reusable fiber, a side firing version (Model 1160), increased indications for any soft tissue application for which Ho:YAG lasers have been cleared, and an increased laser fiber core size range from 200 – 1000 microns.

Construction

The Model 1150 Clarus Straight Firing Fiber is identical in materials, methods of manufacture, sterilization, and dimensions to the currently marketed Clarus Model 1150 Laser Fiber (K922881) with the following exceptions. These exceptions are: making the fiber assembly reusable, increasing the range of the laser fiber core size from 380 - 600 microns to 200 - 1000 microns, and the indications for use. The distal end is polished flat and the laser energy is transmitted in a forward direction. The low OH fiber is terminated on the proximal end with a standard compatible laser connector. These devices consist of an optical fiber, which may be contained in a catheter tube, cannula, needle, handpiece or handle.

The Model 1160 Clarus Side Firing Laser Fiber is built identical to the Model 1150 Clarus Straight Firing Fiber listed above with the following exceptions. The exceptions being that the entire working length of the fiber is in a protective sheath and the distal end is polished at an angle, and then terminated in a quartz cap. The distal tip includes an exit beam indicator that is easily visible to the operator when the fiber is placed through an endoscope. On the proximal end, the low OH fiber is terminated with a standard compatible laser connector.

The Clarus Model 1150 Straight Firing and the Clarus Model 1160 Side Firing Laser Fibers are supplied sterile (ETO) and are intended for reuse.

Use Of Laser Fiber with Delivery system

The Clarus Straight Firing and the Clarus Side Firing Laser Fibers may be used both intraoperatively and percutaneously through regulatory cleared delivery systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tom Barthel
President
Glarus Medical, LLC
1000 Boone Avenue, North
Minneapolis, Minnesota 55427

SEP 3 2002

Re: K021848
Trade/Device Name: Model 1150 Clarus Straight Firing Laser Fiber
Model 1160 Clarus Side Firing Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 4, 2002
Received: June 5, 2002

Dear Mr. Barthel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021947

Statement of Indications for Use

The Clarus Straight Firing Laser Fiber and the Clarus Side Firing Lasers Fiber are for use in general, urological, OB-GYN, orthopedic, and ENT laser surgical procedures for cutting, vaporizing, or coagulating in any soft tissue application for which Ho:YAG lasers have been cleared.

for Mark N Milkers

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021848